REMARKS

With the cancellation of claims 3, 4, 8 and 9, claims 1, 2, 5-7 and 10-26 are pending.

Descriptive support for the amendment to claim1 can be found in claim 4 as filed.

The rest of the claim amendments are editorial and would not narrow the scope of the amended claim recitations. The insertion of "form" into claims 12, 13 and 16-24 is editorial for making it consistent with the term "dosage form" in the preamble of claim 11. The phrase "at least one" is inserted into claim 14 to be consistent with the phrase "at least one" in claim 13. The terms, "maltodextrin", "guar gum", "magnessium aluminum silicate", "powdered cellulose", "pregelatinized starch" and "sodium alginate" are deleted from claim 14 because there terms were recited twice in claim 14. The insertion of the comma after "alginic acid" and the replacement of "sugar;" with "sugar," in claim 19 are editorial. The typographical errors of "gluconic" and "gluconate" are corrected in claim 19.

Claim Rejections -- 35 U.S.C. 102

Applicants respectfully traverse the anticipatory rejections of claims 1-15 over Hiskett (US 5,861,179; hereinafter "the '179 patent").

Without prejudice and without acquiescence with the anticipatory rejections of claims 1 and 3 over Hiskett, applicants have moved the claim recitation of "wherein the diameter of all the lamotrigine particles in the plurality is equal to or less than 50 μm" from claim 4 into claim 1 to advance prosecution. Applicants reserve the right to prosecute claims 1 and 3 as filed in the future.

The '179 patent discloses a pharmaceutical powder formulation of lamotrigine comprising free-flowing granules having a particle size of no greater than 850 μm, wherein at least 90% by weight of the granules have a particle size of from 75 to 850 μm (column 1, lines 17-41). The powder formulation is prepared by a fluid bed granulation process using powders of lamotrigine or a lamotrigine salt, lactose, starch and crystalline cellulose each having average particle sizes below 200 μm (column 3, lines 22-28). The starting lamotrigine or lamotrigine salt powder typically has a particle size of 125 μm or less (column 3, lines 59-60; column 4, lines 41 and 45-46; Example 1

using starting lamotrigine powder of 125 μm). When the input powders are fed into the fluid bed granulation process, the input powders adhere to one another (column 3, lines 37-44), so the resulting granules should be larger than the input powders.

Applicants submit that the '179 patent does not teach every limitation of claims 1, 2, 5-7 and 10-15. For instance, the lamotrigine granules in the pharmaceutical powder formulation of '179 patent do not have diameter equal to or less than 50 μm as recited in the amended claim 1 or equal to or less than 10 μm as recited in claim 5 and having a specific surface area of from about 2 to about 3 ½ square meters per gram because the '179 patent **rejects** any granules that pass through a 75 μm sieve or a 100 μm sieve (see column 3, lines 57-58; column 5, lines 34-36). Withdrawal of the anticipatory rejections is requested.

Claim Rejections -- 35 U.S.C. 103

I. Applicants respectfully traverse the obviousness rejections of claims 1-15 over the '179 patent. Without prejudice and without acquiescence with the obviousness rejections of claims 1 and 3 over Hiskett, applicants have moved the claim recitation of "wherein the diameter of all the lamotrigine particles in the plurality is equal to or less than 50 μm" from claim 4 into claim 1 to advance prosecution. Applicants reserve the right to prosecute claims 1 and 3 as filed in the future.

Claims 1, 2, 5-7 and 10-15 differ from the '179 patent at least in that the lamotrigine particles in the pharmaceutical composition of the '179 patent do not have diameter equal to or less than 50 μm as recited in the amended claim 1 or equal to or less than 10 μm as recited in claim 5 and having a specific surface area of from about 2 to about 3 ½ square meters per gram.

The Office Action asserts that an artisan of ordinary skill would reduce the particle size of the granules of the '179 patent and the artisan would know that the reduced size would logically parlay to an increased specific surface area. The Office Action also asserts that it is within the skill in the art to select optimal parameters such as granular size and specific surface area in order to achieve increased dissolution. Applicants disagree with these assertions of the Office Action. The '179 patent

discloses specifically that any granules that pass through a 75 μm sieve or a 100 μm sieve are **rejected** (see column 3, lines 57-58; column 5, lines 34-36). Thus, there would have been no motivation for the artisan of ordinary skill to modify the granules of the '179 patent to use granules that pass through a 75 μm sieve or a 100 μm sieve.

Another reason why the artisan of ordinary skill would have no motivation to modify the lamotrigine-containing powder formulation of the '179 patent is that the '179 patent discloses that there was no powder formulation of lamotrigine before their invention, and the inventors of the '179 patent prepared **a number of** powder formulations of lamotrigine, but **ONLY ONE** type of powder formulation was proved to be entirely satisfactory (column 1, lines 12, 13 and 17-41) and the one type of powder formulation is the lamotrigine powder formulation disclosed in the '179 patent. If the inventors of the '179 patent told the artisans that they tried a number of powder formulations of lamotrigine, but only the powder formulation disclosed in the '179 patent was entirely satisfactory, the artisans would not have any motivation to modify the powder formulation of lamotrigine disclosed in the '179 patent.

Withdrawal of the obviousness rejections is requested.

II. Applicants respectfully traverse the obviousness rejections of claims 16-24 over the '179 patent in view of Sawyer (US 4,602,017). Claims 16-24 differ from the '179 patent at least in that the lamotrigine particles in the pharmaceutical composition of the '179 patent do not have diameter equal to or less than 50 μm as recited in the amended claim 1 or equal to or less than 10 μm as recited in claim 5 and having a specific surface area of from about 2 to about 3 ½ square meters per gram. The Office Action relies on Sawyer for disclosing the use of pharmaceutical formulations comprising a genus of compounds including lamotrigine for treating CNS disorders. However, Sawyer does not provide any teachings to cure the deficiencies of the '179 patent concerning claims 16-24. As a result, applicants contend that claims 16-24 are not prima facie obvious over the '179 patent in view of Sawyer. Withdrawal of the obviousness rejections is requested.

CONCLUSION

The Examiner is urged to contact the undersigned by phone if there is any issue that can be resolved with a telephone interview.

In the event that the filing of this Response is deemed not timely, applicants petition for an appropriate extension of time. The petition fee, and any other fees that may be required in relation to this paper, can be charged to Deposit Account No. 11-0600.

Respectfully submitted,

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Dated: March 5, 2007

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